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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MELISSA CLARK; BETTY and EVE CASHDOLLAR; ANN RAY, Individually, and as Representative of the Estate of Charles Ray; JOHN and JEANETTE KIMBROUGH; DIANNE MAYER; OZELLA THOMAS, Individually, and as Representative of the Estate of America Watkins; VERNON and DOROTHY DURDEN; PATRICIA and JOHN HURD; MICHAEL BLOUNT; MAISIE JONES, Individually, and as Representative of the Estate of Faye Jones; JORJ and DAN JUDD; JAMES and BEATRICE WILLIAMS; MARIA CORSINO; IRENE DABROWSKI, Individually, and as Representative of the Estate of Irene Leary; CHARLES and JOAN SCHIECK; MADELINE HUFF; CARLOS ESPINOSA and GLORIA GOMEZ; and FAYE and CLAYTON OWENS,	*	
Plaintiffs,	*	
v.	*	**CIVIL CASE # _____**
MERCK & CO., INC., a Domestic Corporation,	*	**JURY TRIAL DEMANDED**
Defendant.	*	

COMPLAINT

COMES NOW, Melissa Clark ("Plaintiff Clark"), Betty and Eve Cashdollar ("Plaintiff Cashdollar"), Ann Ray, Individually, and as Representative of the Estate of Charles Ray ("Plaintiff Ray"), John and Jeanette Kimbrough ("Plaintiff Kimbrough"), Dianne Mayer

("Plaintiff Mayer"), Ozella Thomas, Individually, and as Representative of the Estate of America Watkins ("Plaintiff Thomas"), Vernon and Dorothy Durden ("Plaintiff Durden"), Patricia and John Hurd ("Plaintiff Hurd"), Michael Blount ("Plaintiff Blount"), Maisie Jones, Individually, and as Representative of the Estate of Faye Jones ("Plaintiff Jones"), Jorj and Dan Judd ("Plaintiff Judd"), James & Beatrice Williams ("Plaintiff Williams"), Maria Corsino ("Plaintiff Corsino"), Irene Dabrowski, Individually, and as Representative of the Estate of Irene Leary ("Plaintiff Dabrowski"), Charles and Joan Schieck ("Plaintiff Schieck"), Madeline Huff ("Plaintiff Huff"), Carlos Espinosa and Gloria Gomez ("Plaintiff Espinosa"), and Faye and Clayton Owens ("Plaintiff Owens") complaining of Merck & Co., Inc., (Defendant "Merck"), and for their causes of action against the Defendants states as follows:

Statement of the Parties

1. Plaintiff Melissa Clark is an individual residing in Dahlonega, Georgia, and resident of Lumpkin County, Georgia.

2. Plaintiff Betty Cashdollar is an individual residing in Zuni, Virginia, and a resident of Isle of Wight County, Virginia.

3. Plaintiff Ann Ray is an individual residing in Newnan, Georgia, who brings this suit on behalf of herself, and as representative of Charles Ray.

Ann Ray is the surviving wife of Charles Ray. Plaintiff brings these claims in her capacity as the statutory and common law heir of Decedent and for the lawful wrongful death and survival claims. Plaintiff is the surviving heir of Decedent and the successor in interest to causes of action of Decedent for economic damages, non-economic damages, special damages and punitive damages that survived decedent's death. Plaintiff represents the interests of the Estate of Charles Ray in the instant litigation.

4. Plaintiff John Kimbrough is an individual residing in Freeport, New York, and a resident of Nassau County, New York.

5. Plaintiff Dianne Mayer is an individual residing in Alamo, California, and a resident of Contra Costa County, California.

6. Plaintiff Ozella Thomas is an individual residing in Atlanta, Georgia, who brings this suit on behalf of herself as representative of America Watkins.

Ozella Thomas is the surviving daughter of America Watkins. Plaintiff brings these claims in her capacity as the statutory and common law heir of Decedent and for the lawful wrongful death and survival claims. Plaintiff is the surviving heir of Decedent and the successor in interest to causes of action of Decedent for economic damages, non-economic damages, special damages and punitive damages that survived decedent's death. Plaintiff represents the interests of the Estate of America Watkins in the instant litigation.

7. Plaintiff Vernon Durden is an individual residing in Laganville, Georgia, and a resident of Walton County, Georgia.

8. Plaintiff Patricia Hurd is an individual residing in Newport News, Virginia, and a resident of Newport News County, Virginia.

9. Plaintiff Michael Blount is an individual residing in Norfolk, Virginia, and a resident of Norfolk County, Virginia.

10. Plaintiff Maisie Jones is an individual residing in Longview, Texas, who brings this suit on behalf of herself, and as representative of Faye Jones.

Maisie Jones is the surviving daughter of Faye Jones. Plaintiff brings these claims in her capacity as the statutory and common law heir of Decedent and for the lawful wrongful death and survival claims. Plaintiff is the surviving heir of Decedent and the successor in interest to

causes of action of Decedent for economic damages, non-economic damages, special damages and punitive damages that survived decedent's death. Plaintiff represents the interests of the Estate of Faye Jones in the instant litigation.

11. Plaintiff Jorj Judd is an individual residing in Mesa, Arizona, and a resident of Maricopa County, Arizona.

12. Plaintiff James Williams is an individual residing in Newport News, Virginia, and a resident of Newport News County, Virginia.

13. Plaintiff Maria Corsino is an individual residing in Woodhaven, New York and a resident of Queens County, New York.

14 Plaintiff Irene Dabrowski is an individual residing in Lindenhurst, New York, who brings this suit on behalf of herself, and as representative of Irene Leary.

Irene Dabrowski is the surviving daughter of Irene Leary. Plaintiff brings these claims in her capacity as the statutory and common law heir of Decedent and for the lawful wrongful death and survival claims. Plaintiff is the surviving heir of Decedent and the successor in interest to causes of action of Decedent for economic damages, non-economic damages, special damages and punitive damages that survived decedent's death. Plaintiff represents the interests of the Estate of Irene Leary in the instant litigation.

15. Plaintiff Charles Schieck is an individual residing in Garden City, New York, and a resident of Nassau County, New York.

16. Plaintiff Madeline Huff is an individual residing in Clinchport, Virginia, and a resident of Scott County, Virginia.

17. Plaintiff Carlos Espinosa is an individual residing in Kissimmee, Florida, and a resident of Osceola County, Florida.

18. Plaintiff Faye Owens is an individual residing in Opelousas, Louisiana, and a resident of Saint Landry Parish, Louisiana.

19. Defendant Merck & Co., Inc. (hereinafter referred to as "Merck"), is incorporated in the State of New Jersey and has its principal place of business in White House Station, New Jersey. At all times relevant herein, Merck was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals and other products, including VIOXX®. Defendant Merck can be served through its corporate headquarters at Merck & Co., Inc., One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

20. When the word "Defendant" is used herein, it is meant to refer to the Defendant mentioned in the style of this Complaint, who is liable to Plaintiffs for injuries sustained.

Statement of Jurisdiction and Venue

21. The parties are of diverse citizenship and the amount in controversy exceeds the minimal jurisdictional requirements of the court. Jurisdiction is appropriate in this court, pursuant to 28 U.S.C. §1331(a)(1).

22. Venue is appropriate in this court, pursuant to 28 U.S.C. §1391(a). The Defendant is subject to the Court's jurisdiction, and a substantial portion of the events occurred in New Jersey.

23. The subject matter of this Complaint is also the subject matter of multi-district litigation commenced pursuant to 28 U.S.C. §1407 in MDL No. 1657 in the Eastern District of Louisiana. U.S. District Judge Eldon E. Fallon is the Presiding Judge.

Statement of the Facts

24. This is a civil action brought on behalf of Plaintiff Melissa Clark, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on or about June 2001 as a result.

25. This is a civil action brought on behalf of Plaintiff Betty Cashdollar, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on November 30, 2002 as a result.

26. This is a civil action brought on behalf of Plaintiff Charles Ray, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on January 26, 2004 as a result.

27. This is a civil action brought on behalf of Plaintiff John Kimbrough, who was prescribed and used the prescription medication VIOXX, and suffered strokes on or about August 2002 and December 2004 as a result.

28. This is a civil action brought on behalf of Plaintiff Dianne Mayer, who was prescribed and used the prescription medication VIOXX, and suffered a stroke on or about April 10, 2000 as a result.

29. This is a civil action brought on behalf of Plaintiff America Watkins, who was prescribed and used the prescription medication VIOXX, and suffered a stroke on or about January 12, 2005 as a result.

30. This is a civil action brought on behalf of Plaintiff Vernon Durden, who was prescribed and used the prescription medication VIOXX, and suffered unstable angina on March 19, 2001 as a result.

31. This is a civil action brought on behalf of Plaintiff Patricia Hurd, who was prescribed and used the prescription medication VIOXX, and suffered chest pain on or about September 20, 2004 as a result.

32. This is a civil action brought on behalf of Plaintiff Michael Blount, who was prescribed and used the prescription medication VIOXX, and suffered deep vein thromboses on or about April 2004, October 5, 2004, and November 3, 2004 as a result.

33. This is a civil action brought on behalf of Plaintiff Faye Jones, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack, stroke, and death on April 5, 2004 as a result.

34. This is a civil action brought on behalf of Plaintiff Jorj Judd, who was prescribed and used the prescription medication VIOXX, and suffered a stroke on February 14, 2002 as a result.

35. This is a civil action brought on behalf of Plaintiff James Williams, who was prescribed and used the prescription medication VIOXX, and suffered strokes on or about March 2003 and June 2004 as a result.

36. This is a civil action brought on behalf of Plaintiff Maria Corsino, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on November 26, 2002 as a result.

37. This is a civil action brought on behalf of Plaintiff Irene Leary, who was prescribed and used the prescription medication VIOXX, and suffered cardiac arrest and death on September 10, 2004 as a result.

38. This is a civil action brought on behalf of Plaintiff Charles Schieck, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on or about November 2002 as a result.

39. This is a civil action brought on behalf of Plaintiff Madeline Huff, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on November 15, 2003 as a result.

40. This is a civil action brought on behalf of Plaintiff Carlos Espinosa, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on or about May 2002 as a result.

41. This is a civil action brought on behalf of Plaintiff Faye Owens, who was prescribed and used the prescription medication VIOXX, and suffered a heart attack on or about April 2004 as a result.

42. VIOXX is the brand name of rofecoxib, one of a class of drugs called "prostaglandins," which work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions, arthritis and muscle pain. Prostaglandins are COX (cyclooxygenase) inhibitors; COX enzymes metabolize arachidonic acid to produce prostaglandins.

43. VIOXX is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites, and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.

44. Defendant Merck submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for tablets, at doses of 12.5 mg and 25 mg, for relief of the signs and

symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

45. Defendant Merck also submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for oral suspension, at doses of 12.5 mg/mL and 25 mg/mL, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

46. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 (hereinafter the "NDA") for rofecoxib, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea.

47. At the time the drug was approved by the FDA, the labeling for rofecoxib stated, in the section entitled "Special Studies -- Upper Endoscopy in Patients with Osteoarthritis," "Treatment with VIOXX 25 mg daily or 50 mg daily was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing VIOXX to placebo."

48. The "Warnings" section of the labeling for rofecoxib, at the time the drug was approved by the FDA, contains a section, "Gastrointestinal (GI) Effects -- Risk of GI Ulceration, Bleeding, and Perforation."

49. Defendant Merck submitted sNDA-007 with the goal of establishing a gastrointestinal ("GI") safety claim for rofecoxib. In conjunction with the sNDA, Defendant Merck performed the VIOXX GI Outcomes Research (VIGOR) Protocol, No. 088-04, entitled "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs

During Chronic Treatment With MK-0966 or Naproxen in Patients With Rheumatoid Arthritis: U.S. Cohort." The VIGOR study was performed from January 6, 1999 through March 17, 2000.

50. The objectives of the VIGOR study were to (1) "determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking MK-0966 50 mg daily compared to patients in the group taking naproxen 1000 mg/day," and (2) "study the safety and tolerability of MK-0966 in patients with rheumatoid arthritis."

51. In industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that VIOXX use resulted in a statistically significant increase in hypertension and stroke. Not only did Merck do nothing to further accurately publish these studies, or warn consumers, but it denied the results with respect to hypertension in the official publication of the American Pharmaceutical Association, Pharmacy Today, *Spin War Aside, Lessons Emerge From COX-2 Trials*, in August 2000, page 3.

52. Merck continued to deny the ill health effects associated with VIOXX while at the same time reaping profits obtained through its non-disclosure and concealment. Merck engaged in a massive advertising and sampling program and gained continued increases in the market share, which enhanced Merck's financial stability to the detriment of its consumers. As a result of Merck's scheme, it reaped more than $2 billion in profit in the year 2000 alone, and appropriated approximately 23 percent share of the market.

53. Merck continued to profit from its scheme by withholding information from Plaintiffs, the consuming public, and the health care industry. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine in which

it knowingly downplayed and/or withheld the severity of cardiovascular risks associated with VIOXX consumption over naproxen consumption.

54. On or about August 29, 2001, the Journal of the American Medical Association (JAMA) published a peer-reviewed human epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukherjec, et al., showing what Merck had concealed that the relative risk of developing a "confirmed adjudicated thrombotic cardiovascular event" (defined in the article as "myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks") among VIOXX users in Merck's trials, including VIGOR, at a 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.38 compared to naproxen users, and 4.89 for developing serious cardiovascular events among aspirin-indicated patients. *See* Mukherjec, D., et al., *Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors*, J.A.M.A. 286:8, 954-959, Aug. 22/29,2001. In addition, the annualized myocardial infarction rates for VIOXX users compared to placebo revealed a statistically significant increase among VIOXX users.

55. In the JAMA study, the authors stated that "by decreasing PGI2 production [VIOXX] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PGI2, potentially leading to an increase in thrombotic cardiovascular events." *Id.* at 957. In a follow-up peer-reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the COX-2 inhibitor "tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events." Bing, R., & Lomnicka, M., *Why Do Cyclo-Oxygenase-2 Inhibitors Cause Cardiovascular Events?*, J.A.C.C., 39:3, Feb. 6, 2002. This is further supported by studies completed at the University of Pennsylvania. Cheng,

Y., et al., *Role of Prostacyclin in the Cardiovascular Response to ThromboxaneA2*, Journal of Science, V. 296:539-541, Apr. 19, 2002.

56. On September 17, 2001, Thomas W. Abrams, R.Ph., MBA, Director of the FDA Division of Drug Marketing, Advertising, and Communications, issued a "Warning Letter" to Raymond V. Gilmartin, President and CEO of Defendant Merck, relating to "promotional activities and materials for the marketing of VIOXX (rofecoxib) tablets."

57. The Warning Letter stated that Defendant Merck had "engaged in a promotional campaign for VIOXX that minimizes the potentially serious cardiovascular findings that were observed in the VIOXX Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for VIOXX." The letter further states:

> Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on VIOXX were observed to have a four to five fold increase in myocardial infarctions (Mis) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

58. The eight (8) page Warning Letter outlines, in detail, the conduct of Defendant Merck that supports the FDA's issuance of the Warning Letter, and makes the following **"Conclusions and Requested Actions:"**

> The promotional activities and materials described above minimize the potentially serious Cardiovascular findings that were observed in the VIGOR study, minimize the VIOXX / Coumadin drug interaction, omit crucial risk information associated with VIOXX therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for VIOXX that misrepresented VIOXX'S safety profile, contained unsubstantiated comparative claims, and lacked fair balance.
>
> Due to the seriousness of these violations, and the fact that your violative promotion of VIOXX has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001.
>
> This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the

audiences that received these misleading messages. This corrective action plan should also include:

> Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for VIOXX.
>
> Issuing a "Dear Healthcare provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.
>
> A written statement of your intent to comply with "1" and "2" above.

59. On April 11, 2002, the FDA approved a supplemental application for the use of VIOXX (rofecoxib) for rheumatoid arthritis, adding this indication to the previously approved indications for osteoarthritis and pain. The FDA also approved new labeling, a "Dear Doctor" letter, and a new patient package insert. The labeling and the "Dear Doctor" letter contained information concerning the results of the VIGOR study.

60. The revised labeling further states that the administration of VIOXX 50 mg., was associated with a higher incidence of gastrointestinal symptoms.

> ***Clinical Studies in OA and KA with VtOXX 5Q mg (Twice the highest* rfuse *rectmwtended far chronic tael***
> In OA and RA clinical trials which contained VIOXX 12.5 or 25 mg as well as VIOXX 50 nig. VIOXX 50 mg OD was associated with *a* higher incidence of gastrointestinal symptoms (abdominal pain, epigastric pain, heartburn, nausea and vomiting), lower extrernit/ edema, hypertension, serious* adverse experiences and discontinuation due to clinical adverse experiences compared to the recommended chronic doses of 12.5 and 25 ma l'see DOSAGE AND ADMINISTRATION!.

61. Further, the "Dear Doctor" letter, approved in conjunction with the revisions to the VIOXX labeling, outlines the changes to the VIOXX labeling.

62. The revised "Patient Information" sheet does not add any information about the results of the VIGOR study.

63. The "Patient Information" sheet is the only written document that is provided to a patient for whom VIOXX is prescribed.

64. Both the initial labeling and the revised labeling are ineffective because they do not properly advise physicians and patients of the potential gastrointestinal side effects of VIOXX.

65. Despite knowledge of the ineffectiveness of the warnings, and despite knowledge that VIOXX may cause serious gastrointestinal side effects, Defendant Merck has concealed and/or downplayed the dangers associated with VIOXX, and continues to market the drug in the United States and abroad. In its 2001 Annual Report, for example, Defendant Merck states:

> The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to *Vioxx*. . . . The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

66. Further, in its January 23, 2001 8-K filing with the Securities and Exchange Commission, the Defendant failed to mention the cardiac and cardiothrombotic findings of the VIGOR study:

> "Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, **VIOXX**, ZOCOR, COZAAR/HYZAAR*, FOSAMAX and SINGULAIR, drove Merck's performance for the year and created a powerful platform for growth." These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter.
>
> "Each of the five medicines offers unique competitive advantages," Mr. Gilmartin said. **VIOXX**, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, **VIOXX** has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, **VIOXX** now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States. **VIOXX** achieved $2.2 billion in sales for the full year 2000, with $700 million in the fourth quarter.

> A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, in which **VIOXX** reduced the risk of serious gastrointestinal complications by half compared to the NSAID naproxen, was published in November in THE NEW ENGLAND JOURNAL OF MEDICINE. Another study, presented in November, showed that **VIOXX** significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.

67. Despite the foregoing, Defendant Merck has continued to represent to consumers that VIOXX is safe, and that any cardiovascular and/or cardiothrombotic side effects are not associated with the drug. The Defendant has also downplayed any potential gastrointestinal side effects of the drug, promoting it as safe and more efficacious than other medications approved for treatment of similar conditions.

COUNT I
PRODUCTS LIABILITY - DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 *et seq.*)

68. Plaintiffs repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

69. Defendant is the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of VIOXX, which is defective and unreasonably dangerous to consumers.

70. VIOXX is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. VIOXX is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other nonsteroidal anti-inflammatory medicines and similar drugs on the market and is more dangerous than ordinary consumers can reasonably foresee.

71. The defective condition of VIOXX renders it unreasonably dangerous, and VIOXX was in this defective condition at the time it left the hands of the Defendant. VIOXX was expected to and did reach consumers, including all Plaintiffs, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

72. Plaintiffs were unaware of the significant hazards and defects in VIOXX. VIOXX was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiffs were taking VIOXX, the medication was being utilized in a manner that was intended by Defendant. At the time Plaintiffs received and consumed VIOXX, it was represented to be safe and free from latent defects.

73. Defendant Merck is strictly liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendant because of the design defects.

74. Defendant Merck knew or should have known of the danger associated with the use of VIOXX, as well as the defective nature of VIOXX, but has continued to design, manufacture, sell, distribute, market, promote and/or supply VIOXX so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by VIOXX.

75. As a direct and proximate cause of the design defect and Defendant's misconduct as set forth herein, Plaintiffs suffered and continue to suffer serious and permanent physical and emotional injuries, have expended, and will continue to expend large sums of money for medical

care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiffs demand judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
PRODUCTS LIABILITY - FAILURE TO WARN (N.J.S.A. 2A:58C-2 *et seq.*)

76. Plaintiffs repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

77. Defendant Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, VIOXX, and in the course of same, directly advertised or marketed the product to FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of VIOXX.

78. VIOXX was under the exclusive control of the Defendant as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of VIOXX, dangerous drug-drug interactions and food-drug interactions, and the comparative severity, duration and the extent of the risk of injury with such use.

79. Defendant Merck has failed to timely and reasonably warn of material facts regarding the safety and efficacy of VIOXX so that no medical care provider would have prescribed, or no consumer would have used, VIOXX had those facts been made known to such providers and consumers.

80. Defendant Merck has failed to perform or otherwise facilitate adequate testing in that such testing would have shown that VIOXX posed serious and potentially life-threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including Plaintiffs.

81. VIOXX, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendant, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendant knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of VIOXX, Defendant failed to provided adequate warnings to medical care providers, the FDA and the consuming public, including Plaintiffs, and continued to promote VIOXX aggressively.

82. As direct and proximate result of the conduct of Defendant Merck as aforesaid, Plaintiffs suffered and continue to suffer serious and permanent physical and emotional injuries, have expended, and will continue to expend large sums of money for medical care and treatment, suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiffs demand judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
NEW JERSEY CONSUMER FRAUD ACT (N.J.S.A. 56:8-*2 et seq.*)

83. Plaintiffs repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

84. Prescription drugs such as VIOXX are "merchandise," as that term is defined by NJ.S.A. 56:8-1 *et seq.*

85. Defendant Merck is the researcher, developer, designer, tester, manufacturer, inspector, labeler, distributor, marketer, promoter, seller and/or otherwise released VIOXX into the stream of commerce.

86. Defendant Merck knew or should have known that the use of VIOXX causes serious and life threatening injuries but failed to warn the public, including Plaintiffs, of same.

87. In violation of the Act, Defendant Merck made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from Plaintiffs in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of VIOXX. Moreover, Defendant downplayed and/or understated the serious nature of the risks associated with VIOXX in other to increase the sales of VIOXX and secure a greater share of the COX-2 market.

88. Defendant's statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including Plaintiffs, would rely on the Defendant's statements and/or omissions.

89. Defendant knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of VIOXX but remained silent because Merck's appetite for significant future profits far outweighed its concern for the health and safety of Plaintiffs.

90. Plaintiffs' physicians prescribed and/or otherwise provided Plaintiffs with VIOXX, and Plaintiffs consumed VIOXX, primarily for personal and family reasons and

suffered ascertainable losses of money as a result of the Defendant's use or employment of the methods, acts, or practices alleged herein.

91. The aforesaid promotion and release of VIOXX into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connection with the sale or advertisement of such merchandise or services by Defendant, in violation of the New Jersey Consumer Fraud Act., N.J.S.A. 56:8-1 *et seq.*

92. Defendant Merck concealed, omitted, or minimized the side effects of VIOXX or provided misinformation about adverse reactions, risks and potential harms from VIOXX and succeeded in persuading consumers to purchase and ingest VIOXX despite the lack of safety and the risk of adverse medical reactions, including cardiovascular events and gastrointestinal effects.

93. Defendant Merck's practice of promoting and marketing VIOXX created and reinforced a false impression as to the safety of VIOXX, thereby placing consumers at risk of serious and potential lethal effects.

94. VIOXX lacked appropriate warnings, and the packaging and labels used by Defendant were misleading, inaccurate, incomplete, and/or untimely.

95. Defendant Merck violated its post-manufacture duty to warn which arose when Merck knew, or with reasonable care should have known, that VIOXX was injurious and sometimes fatal.

96. At the time when consumers purchased and ingested VIOXX, Defendant Merck intended that others would rely upon the concealment, suppression or omission of the risks of ingesting VIOXX.

97. Defendant's actions in connection with manufacturing, distributing, and marketing of VIOXX as set forth herein evidence a lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the New Jersey Consumer Fraud Act., N.J.S.A, 56:8-2 *et seq.*

98. Defendant Merck acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

99. As a proximate result of the acts of consumer fraud set forth above, Plaintiffs purchased an unsafe product and incurred monetary expense and the risk to themselves and members of their households that they would consume VIOXX and thereby suffer an increased risk of harm as previously set forth herein.

WHEREFORE, Plaintiffs demand judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

100. Plaintiffs repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

101. Defendant Merck placed VIOXX into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including the Plaintiffs, of the risks associated with the use of VIOXX.

102. Defendant Merck had a duty to exercise reasonable care in the research, development, design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of VIOXX, including a duty to:

a) Ensure that the product did not cause the user unreasonably dangerous side effects;

b) Warn of dangerous and potentially fatal side effects; and

c) Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiffs.

103. When Plaintiffs' physicians prescribed VIOXX and Plaintiffs made the decision to use VIOXX, both Plaintiffs and their physicians reasonably relied upon the Defendant and its agents to disclose known defects, risks, dangers and side effects of VIOXX.

104. Plaintiffs' physicians, the FDA and/or Plaintiffs had no knowledge of the falsity or incompleteness of the Defendant's statements and representations concerning VIOXX when Plaintiffs' physicians prescribed and/or otherwise provided VIOXX and Plaintiffs purchased and used VIOXX as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendant. Plaintiffs justifiably and detrimentally relied on the warranties and representations of Defendant in the purchase and use of VIOXX.

105. Defendant Merck was under a duty to disclose the defective and unsafe nature of VIOXX to physicians, the FDA, consumers and users, such as Plaintiffs. Defendant had sole access to material facts concerning the defects, and Defendant knew that physicians, the FDA and users, such as Plaintiffs, could not have reasonably discovered such defects.

106. By the conduct alleged, Defendant Merck, its agents and employees expressly warranted to Plaintiffs and Plaintiffs' physicians that the products were merchantable and fit for the purpose intended, in violation of N.J.S.A. 12A:2-313 *et seq.*

107. This warranty was breached because VIOXX was not safe and effective as a medication for arthritis and pain, as Defendant had represented, and Plaintiffs were injured.

108. As a direct result of Defendant's conduct aforesaid, Plaintiffs suffered and continue to suffer serious and permanent physical and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiffs demand judgment against Defendant Merck for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
PUNITIVE DAMAGES UNDER THE PRODUCTS LIABILITY ACT (N.J.S.A.2A:58C-1)

109. Plaintiffs repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

110. Plaintiffs are entitled to punitive damages because the Defendant's failure to warn was reckless and without regard for the public's safety and welfare. The Defendant misled both the medical community and the public at large, including Plaintiffs, by making false representations about the safety of VIOXX. Defendant downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of VIOXX despite available information demonstrating that VIOXX was likely to cause serious and even fatal side effects to users.

111. Defendant was or should have been in possession of evidence demonstrating that VIOXX caused serious side effects. Nevertheless, Defendant continued to market VIOXX by providing false and misleading information with regard to safety and efficacy.

112. Defendant failed to provide warnings that would have dissuaded physicians from prescribing VIOXX and consumers from purchasing and consuming VIOXX, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming VIOXX.

WHEREFORE, Plaintiffs demand judgment against Defendant Merck for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

RELIEF REQUESTED

WHEREFORE, Plaintiffs demand judgment against Defendant Merck as follows:

A. Award Plaintiffs compensatory damages against Defendant in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;

B. Award Plaintiffs treble damages against Defendant so to fairly and completely compensate Plaintiffs for all damages, and to deter similar wrongful conduct in the future;

C. Award Plaintiffs punitive damages against Defendant in an amount sufficient to punish Defendant for its wrongful conduct and to deter similar wrongful conduct in the future;

D. Award Plaintiffs costs and disbursements, costs of investigations, attorneys' fees and all such other relief available under New Jersey law;

E. Award that the costs of this action be taxed to Defendant; and

F. Award such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury.

Dated: September 27, 2006

Respectfully Submitted,

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